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510(K) SUMMARY

OPUSDUO EC DENTAL LASER SYSTEM

510(k) Number K 021508 1/4

Applicant's Name:

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Contact Person:

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Date Prepared:

April 2002

Trade Name:

OpusDuo EC Dental Laser System

Classification Name:

Laser Instrument, Surgical, powered

Classification:

Laser Instrument, Surgical, Powered are class II devices (Product Code GEX).

Predicate Device:

The Opus20/Opus Spectrum/Opus Duo EC Dental Laser System with the additional periodontal, endodontal and soft tissue indications for the Erbium component and the additional periodontal indications for the CO2 component, "OpusDuo EC", is substantially equivalent to the same system (Opus 20 and Opus Spectrum/OpusDuo Dental Laser System) previously cleared for other indications under K002899 and K014100, respectively, in terms of technological characteristics and specifications, mechanism of action and user interface.

The Erbium component of the OpusDuo EC Dental Laser System with the additional periodontal, endodontal and soft tissue indications is substantially equivalent to a combination of the following erbium laser systems cleared by the FDA:

- KaVo KEY Laser 1242 (KaVo America Corporation) cleared under K983100
- FuturLase 3000/3002 Erbium Laser System (Pharos Optics, Inc.) cleared under K974641
- Pulsemaster Erbium Dental Laser (American Dental technologies, Inc.) cleared for hard and soft tissues indications under K012127
- Pulsemaster Erbium Dental Laser (American Dental technologies, Inc.) cleared for periodontic indication under K961269
- WaterLase Millennium Dental Laser System (BioLase Technology, Inc.) cleared under KO11041
- WaterLase Millennium Dental Laser System (BioLase Technology, Inc.) cleared for additional endodontic indications under K012511

The CO2 component of the OpusDuo EC with the additional periodontal indications is substantially equivalent to a combination of the Opus 20 and Opus Spectrum/Opus Duo cleared under K002899 and K014100, respectively, the Uni-CO2 450P CO2 Laser System (Medart Corp.), cleared under K991297 and the Opus 10™ Diode Laser (OpusDent Ltd.) cleared under K000990.

Performance Standards:

The OpusDuo EC Dental Laser complies with:
U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.
In accordance with FDA's guidance "Use of Standards in Substantial Equivalence Determinations", OpusDent is declaring that the OpusDuo EC confirms to EN 60601-1 and EN 60601-1-2.
In addition, the device complies with the voluntary standards, EN-601-2-22, EN-60825-1, CISPR 11: 1997, class B and IEC 61000-4-2/3/4/5: 1995, EMI – EN55011 :1991, IEC 801:1991 as described in Section 5.

In compliance with these standards, OpusDuo EC is equipped with:
Interlock protective housing, laser emission indicators, beam shutters, energy and power display, master key switch, emergency shut-off knob, remote interlock connector and proper labeling.

Intended Use / Indication for Use:

The OpusDuo EC Dental Laser System is intended to aid during dental procedure performed either in hard or soft oral tissue.

The Er:YAG laser component is indicated for caries removal, cavity preparation, enamel etching and the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry.

The CO2 laser component is indicated for periodontal procedures such as removal of diseased or inflamed soft tissue in the periodontal pocket (subgingival debridement) and vaporization, incision, excision, coagulation and ablation of oral soft tissue in procedures such as gingivectomy; frenum release; removal of soft tissue, cysts and tumors.

Device Description:

The OpusDuo EC is a model of the Opus 20 Dental Laser System, which is intended to aid during dental procedures performed either in hard or soft oral tissue. This is a dual laser system incorporating an Er:YAG laser and a CO2 laser. The system is operating at a wavelength of 2.94 microns and 10.6 microns respectively. The Er:YAG laser delivers to the tissue pulses with energies up to 1 joule per pulse and power up to 12 Watts. The CO2 laser delivers to the tissue power in continuous mode (CW) up to 10 Watts and pulses (SP) up to 6 Watts.

Substantial Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The OpusDuo EC intended use and indications for use were previously cleared by FDA for the predicate devices.

- The technical characteristics of both the Er:YAG and CO2 lasers of the OpusDuo EC system are basically the same as those of the cleared Opus 20 (K002899) and its new model Opus Spectrum/Opus Duo (K014100).
  The Er:YAG component of the OpusDuo EC has the same or very similar technical characteristics as its predicates; the KaVo, the FutureLase , the Pulse Master and the WaterLase, including theory of operation, laser medium and the ability to deliver the same wavelength (or very close value, in the case of WaterLase) at a similar average power and pulse rate.
  The CO2 component of the OpusDuo EC has the same or very similar technical characteristics including theory of operation, laser medium and the ability to deliver the same wavelength at the same maximal power pulse rate and pulse duration as its predicate device, the Uni-CO2 450P system.

- Laser output values of the OpusDuo EC are well within previous cleared values of the predicate devices as described.

- The predicate devices and other previous cleared lasers with similar energy output have a proven safety and effectiveness in the treatment of the claimed indications.

K021508 4/4

- Validation testing has confirmed that the design of the additional accessories, which are required for the new applications, satisfies their technical specification.

Therefore, we believe that the *OpusDuo EC* Dental Laser System is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 7 2002

OpusDent Ltd.
c/o Dorit Winitz, Ph.D.
Push-Med Ltd.
117 Ahuzah Street
Ra'ananna, 43373
Israel

Re: K021508
Trade/Device Name: OpusDuo EC Dental Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 5 2002
Received: May 9, 2002

Dear Dr. Winitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as setforth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K021508

Device Name: OpusDuo EC

Indications for Use:

The OpusDuo EC Dental Laser System is intended to aid during dental procedures performed either in hard or soft oral tissue.

- The Er:YAG laser component is indicated for caries removal, cavity preparation, enamel etching and the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry. These include the following:

Soft tissue and periodontal indications	Endodontal applications
• Excisional and incisional biopsies • Exposure of unerupted teeth • Incision and drainage of abscesses • Gingival incision and excision • Gingivoplasties • Gingivectomies, Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias • Gingival troughing for crown impressions • Hemostasis • Implant recovery • Frenectomies and frenotomies • Fibromatosis (fibroma removal) • Benign and malignant lesion removal • Operculectomy • Oral papillectomies • Reduction of gingival hypertrophy • Soft tissue crown lengthening • Preprosthetic surgery; flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasias, epulides, papilomas, fibromatoses, benign growths • Vestibuloplasty • Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)	• Tooth preparation to obtain access to root canal • Pulpotomy • Pulp extirpation • Pulpotomy as an adjunct to root canal therapy • Root canal debridement and cleaning • Root canal preparation including enlargement for Mark N Milham (Division Sign-Off) Division of General, Restorative and Neurological Devices 510(k) Number K021508

- The CO2 laser component is indicated for periodontal procedures such as removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement) and vaporization, incision, excision coagulation and ablation of oral soft tissue in procedures such as gingivectomy; frenum release; removal of soft tissue, cysts and tumors.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)